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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

15

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,463

Applicant(s)

LIU ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-87, 90-92, 96-106, 109-119, 122-125, 131-134 and 138-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 98-106, 109-119, 122-125, 131-134 and 138-141 is/are allowed.
- 6) ☒ Claim(s) 73-87, 90-92, 96-97 and 142-151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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Detailed Action

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73-79, 81, 144 and 146 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is necessitated by applicants' amendment filed 6/18/03. Applicants have broadened the scope of claims 73-19, 81, 144 and 146 to recite that the baculovirus need not be considered an insect control agent and that the baculovirus direct transcription of any RNA that forms a double stranded (ds) structure that inhibits expression of any gene in any cell (which can include mammalian cells or any cells from any organism which is not a pest organism). Applicants cite sections of the specification that allegedly support this amendment and indicate that the prior art teaches that baculoviruses can direct gene expression in a wide variety of cells, including mammalian cells and that dsRNA operates to inhibit gene expression in a wide variety of cells.

The specification, as filed, does not provide support for the scope of the amended claims. The portions of the specification cited by applicants as supporting the claim amendments do not provide support for baculovirus agents which can infect any

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cells and direct transcription of RNAs which form dsRNA structures that inhibit expression of any gene in any cell from any organism. The instant specification recites recombinant baculoviruses as pest control agents directed against the insects (or other pest organisms) that can be infected with the baculoviruses. The disclosed baculoviruses function as pest control agents by directing formation of inhibitory dsRNA. The specification does not provide support for baculoviruses which direct transcription of an RNA which forms a ds structure that inhibits expression of any gene in any cell from an organism which is not an insect or other pest organism. THIS IS A NEW MATTER REJECTION.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 73, 79-87, 90 and 142 and 151 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al.

This rejection is maintained for reasons of record in the previous Office Action (Paper #12) and for reasons outlined below.

Applicants traverse this rejection by asserting that Adams et al. does not teach the limitation that the RNA forms a double stranded structure that inhibits expression of

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at least one gene in the target cell. Applicants assert that Adams et al. teaches traditional antisense approaches to target gene expression inhibition while applicants utilize dsRNA inhibition of expression of target genes. Applicants assert that Adams et al. clearly recites vectors that express sense sequences for over-expression of target sequences or antisense sequences for inhibition of target genes and that Adams et al. does not recite baculovirus vectors having both sense and antisense sequences directed against the same target gene. Applicants assert that at most Adams et al. teaches baculoviruses comprising sense sequences for causing over expression of one or more target genes and antisense sequences directed against inhibiting the expression of different target gene(s). Applicants assert that it would be illogical to include sense and antisense sequences targeted against the same gene because these would cancel each other out.

Applicant's arguments filed 6/18/03 have been fully considered but they are not persuasive. Applicants are incorrect in asserting that Adams et al. does not teach that the RNA forms a double stranded structure that inhibits expression of at least one gene. It is noted that claim 73 (upon which the other rejected claims depend), for example, merely recites a baculovirus which directs transcription of at least one RNA that forms a ds structure that inhibits expression of at least one gene. A baculovirus which expresses an antisense RNA targeted to a gene would result in the formation of a ds structure (comprising the antisense RNA and the target sequence) capable of inhibiting expression of the target gene. This is the essence of antisense based inhibition of gene expression and is well known in the art. For example, Jennings et al. (U.S. Patent

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5,298,612, issued 03/29/94) defines "antisense" as follows: "By "antisense" is meant the formation of a duplex or double stranded sequence as a result of base pairing between complementary bases of a target sequence and an antisense oligonucleotide..."

(Column 8, lines 33-36). Citation of secondary evidence to show that a characteristic not disclosed in an anticipatory reference is inherent is permissible here (See MPEP 2131.01).

Applicants' assertions with regard to the absence of teachings by Adams et al. on the generation of baculoviruses containing sense **and** antisense sequences directed against the same target gene is, largely, agreed with. Additionally, it is noted that while Adams et al. does recite that sense and antisense sequences against a single gene can be engineered into a baculovirus, there is not teachings that the sense and antisense sequences would be complementary. A fair reading of the rest of the Adams et al. reference, in light of applicants' arguments, would indicate that Adams et al. did not contemplate a baculovirus expressing complementary sense **and** antisense sequences directed against the same target gene. The 102(e) rejection against claim 74 is therefore withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. in view of Miller et al.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants traverse this rejection by asserting that since Adams et al. does not teach the recited baculovirus agents, the teachings of Adams et al. in view of Miller does not render the claim obvious.

Applicants' arguments have been considered but are not persuasive. Since Adams et al. does constitute anticipatory art against the base claim (73) for reasons cited in the above 35 USC 102(e) rejection, the rejection of claim 91 over Adams et al. in view of Miller et al. stands for reasons of record.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 73-77, 79, 142, 143 and 144 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,326,193. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a baculovirus which is capable of directing expression of at least one RNA that forms a double stranded (ds) structure. The instant claims are broader in scope than the claimed subject matter in the '193 patent. It is noted that the expression of complementary sense and antisense sequences recited in the '193 patent would result in the formation of ds structures. The instant claims differ from those recited in the '193 patent in that the instant claims recite that the ds structure inhibits expression of at least one gene. However, the baculovirus recited in the '193 patent is designed to express ds structures comprising RNAs homologous to insect genes which would inherently result in dsRNA inhibition of expression of the target gene.

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Claims 80-87, 90, 92, 96, 142-151 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,326,193 in view of Adams et al.

The essential features of the instant recombinant baculoviruses are claimed in the '193 patent. The '193 patent does not recite the instantly claimed target insect genes, cells and tissues as well as the target insects and baculoviruses used to generate the recombinant baculovirus agents and insecticidal compositions. Adams et al. (cited as in the above 102(e) rejection) recites that the genes to be inhibited in insects include essential genes such as those involved in development (ETH gene) or genes in tissues such as the alimentary canal of *Manduca sexta*, use of the *Autographa californica* NPV (AcNPV) to deliver the inhibitory sequences, insecticidal compositions comprising recombinant baculoviruses and agriculturally acceptable carriers. The ordinary skilled artisan, seeking to choose the insect genes to be inhibited, would have been motivated to choose essential genes such as those recited by Adams et al. because inhibition of these genes would have the expected benefit of increasing the effectiveness of the baculovirus as a pesticide. The ordinary skilled artisan would have been motivated to target an insect like *M. sexta* because this species is a agriculturally important pest and said skilled artisan would have been motivated to choose the AcNPV as the baculovirus because this virus is well characterized and has been used to express foreign genes as noted by Adams et al. It would have been obvious for the ordinary skilled artisan to do this because Adams et al. teaches the expected benefits (more effective pesticides) of using recombinant baculoviruses comprising sequences

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targeting essential genes in insect pest organisms such as *M. sexta*. Given the teachings of the cited claims and prior art and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 91 and 97 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,326,193 in view of Adams et al. and Miller et al.

Applicants recite insecticidal compositions comprising sticking agents or UV protectants.

Adams et al. is cited as in the above 35 USC 102(e) and obviousness type double patenting rejections. The '193 patent and Adams et al. do not recite insecticidal compositions comprising standard components such as UV protectants and sticking agents.

Miller et al. (U.S. 6,235,278, issued 5/22/01, filed 10/1/97, see whole document, particularly column 21) recites the use of standard agriculturally acceptable carriers for administration of recombinant baculovirus insect control agents and the use of agents such as UV protectants and sticking agents in said agriculturally acceptable carriers.

The ordinary skilled artisan, seeking to apply the recombinant baculoviruses recited in the '193 patent and Adams et al. reference, would have been motivated to include standard additives such as UV protectants or sticking agents (as recited by

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Miller et al.) into the agriculturally acceptable carriers recited by Adams et al. for their known and expected benefits (e.g. increasing the potency or efficacy of the baculovirus pest control agents) as recited by Miller et al. It would have been obvious for the ordinary skilled artisan to do this because the use of agents such as UV protectants or sticking agents in agriculturally acceptable carriers increases the efficacy of the biocontrol agents such as recombinant baculoviruses contained in said carriers (as recited by Miller et al.). Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Any rejections not repeated in this Office Action are withdrawn.

Claims 98-106, 109-119, 122-125, 131-134 and 138-141 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 22, 2003

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Miller et al.) into the agriculturally acceptable carriers recited by Adams et al. for their known and expected benefits (e.g. increasing the potency or efficacy of the baculovirus pest control agents) as recited by Miller et al. It would have been obvious for the ordinary skilled artisan to do this because the use of agents such as UV protectants or sticking agents in agriculturally acceptable carriers increases the efficacy of the biocontrol agents such as recombinant baculoviruses contained in said carriers (as recited by Miller et al.). Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

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David Guzo
August 22, 2003


DAVID GUZO
PRIMARY EXAMINER